DEPARTMENT OF HEALTH & HUMAN SERVICES

Office of the Secretary
Office of Public Health and Science

FOR US POSTAL SERVICE DELIVERY:
Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01
Institutes of Health (MSC 7507)
Rockville, Maryland 20892-7507

FOR HAND DELIVERY OR EXPRESS MAIL:
Office for Human Research Protections
6100 Executive Boulevard, Suite 3B01 National
Rockville, Maryland 20852

Telephone: 301-402-5567
FAX: 301-402-2071
E-mail: mc2a@nih.gov

August 20, 2001

Neal Nathanson, M.D.
Vice Provost for Research
110 College Hall
University of Pennsylvania
Philadelphia, PA 19104

Mary Chatterton, J.D.
Secretary
Monell Chemical Senses Center
3500 Market Street
Philadelphia, PA 19104-3308

RE: Human Research Subject Protections Under Multiple Project Assurance (MPA) M1025

Research Project: Perception of Acetone; IRB #192101
Principal Investigator: Charles J. Wysocki
HHS Project Numbers: RO1 DC-00298; P50 DC00214; F32 DC-00197

Dear Dr. Nathanson and Ms. Chatterton:

The Office for Human Research Protections (OHRP) has reviewed your July 25, 2001 report regarding the above referenced research that was submitted in response to OHRP's June 20, 2001 letter.

Based upon its review, OHRP finds that the University of Pennsylvania (U Penn) and Monell Chemical Senses Center (Monell) have developed a satisfactory plan for debriefing subjects who participated in the above referenced research. In particular, OHRP acknowledges that the debriefing text provided with your letter includes the following: (i) an accurate explanation of the purpose of the research; (ii) a simple, complete, and accurate description of all research procedures that the subjects underwent; (iii) the names and approximate levels of all chemicals to which the subjects were exposed, and the known exposure safety limits for each chemical; (iv) a description of the reasonably foreseeable risks and discomforts of the research; (v) a description of any benefits to the subjects or others that may have resulted from the research; and (vi) an explanation of whom to contact if the subjects have any questions about their rights as

research subjects. Furthermore, OHRP acknowledges that U Penn and Monell have developed an adequate plan to help subjects cope with, and recover from, any anxiety that may be engendered by the debriefing process.

OHRP notes that the debriefing text provided with your letter is directed at factory worker subjects who participated in the above referenced research. OHRP presumes that similar debriefing texts have been or will be prepared for the *non-factory workers exposed to acetone* and *the non-acetone exposed subjects* who participated in either Study I ("Determining the Irritation Threshold for Acetone: Detection and Lateralization Study") or Study II ("Evaluating the Perceptual Response to Acetone: Judgements of Intensity and Irritation") of the above referenced protocol. OHRP requests that U Penn and Monell submit to OHRP a representative debriefing letter sent to each group of subjects (with redaction of all subject identifiers) as soon as the letters are issued.

Presuming full implementation of the debriefing plan by U Penn and Monell for all three groups of subjects who participated in the above-referenced research, there should be no need for further involvement of OHRP in this matter. As a result, OHRP is closing its compliance oversight evaluation of the above-referenced research. Of course, OHRP must be notified should new information be identified which might alter the above determination.

OHRP appreciates your institutions' commitment to the protection of human subjects. Please do not hesitate to contact me should you have any questions.

Sincerely,

Michael A. Carome, M.D.
Director, Division of Compliance Oversight

cc: Dr. Greg Koski, OHRP
Dr. Melody Lin, OHRP
Mr. George Gasparis, OHRP
Ms. Roslyn A. Edson, OHRP
Dr. Jeffrey Cohen, OHRP
Mr. Barry Bowman, OHRP
Dr. Joseph Sherwin, Director of Regulatory Affairs, U Penn
Dr. Nicholas Kefalides, IRB Executive Chair, U Penn
Dr. Charles J. Wysocki, Monell
Commissioner, FDA
Dr. David Lepay, FDA
Dr. James F. McCormack, FDA